OIG Responses to Additional Questions from Chairman Pitts Regarding the 340B Program
May 4, 2015

1. HRSA had been preparing a regulation to address the definition of a patient and hospital eligibility, but withdrew its proposal last year following a May 2014 federal district court ruling which found that HRSA's rulemaking authority for the 340B Program is limited to specified areas. HRSA has explained that the agency will be proposing *guidelines* later this year to address those issues. However, as a practical matter, HRSA will be effectively just writing suggestions they have little ability to enforce. Are you aware of any other health care agency in recent history whose hands have been tied in this manner, by not being able to write rules governing the program they administer? In the interest of government accountability and program integrity, is this concerning to you?

   OIG is not aware of other HHS agencies in the position of having to run a program on guidance alone. OIG concurs that enforceable rules are important for accountability and program integrity. In addition to having rules that are enforceable, the rules should be clear and specific so that all stakeholders understand how they will be interpreted and enforced. A 2014 OIG report entitled *Contract Pharmacy Arrangements in the 340B Program* (OEI-05-13-00431) noted a lack of clarity and specificity in HRSA guidance with regard to contract pharmacies.

2. Your testimony noted more transparency is needed in the 340B program's ceiling prices and Medicaid Claims data for 340B-purchase drugs. What should Congress do to fix HRSA's transparency problems?

   OIG work has shown that a lack of both price and claims transparency creates program integrity vulnerabilities in the 340B Program. Congress has already taken steps to address some of these vulnerabilities, but there are additional steps it can take to ensure stakeholders have the information they need to strengthen program integrity.

   To improve price transparency, in the Patient Protection and Affordable Care Act (ACA), Congress required that HRSA share ceiling prices with covered entities. This will allow covered entities to verify that they are not being overcharged by manufacturers. HRSA has said it plans to implement a system to do so this year.

   To further address vulnerabilities related to the lack of price transparency, Congress could give HRSA authority to share ceiling prices with States, per an outstanding recommendation from a 2011 OIG report entitled *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs* (OEI-05-09-00321). This would allow States to more accurately pay according to their Medicaid reimbursement policies.

   To address the lack of 340B claims transparency, Congress could encourage CMS and HRSA to continue working with 340B providers and State Medicaid agencies to address vulnerabilities. Transparency as to which Medicaid claims represent 340B-purchased drugs is essential to States' efforts to pay correctly and would help them protect manufacturers from duplicate discounts.

Further action may be needed to ensure claims transparency for 340B-purchased drugs reimbursed by Medicaid Managed Care Organizations (MCOs). Ongoing OIG work is exploring tools that States use with Medicaid MCOs, which may result in recommendations to HRSA or CMS. OIG would be pleased to brief you on the results of that work when it is complete, as well as provide further technical assistance.

3. What are best practices for CMS, HRSA, and the states to prevent duplicate 340B discounts and Medicaid rebates?

   OIG's 2011 report, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs* (OEI-05-09-00321), described the array of tools that States use to identify claims for 340B-purchased drugs when claiming Fee-For-Service (FFS) Medicaid rebates. In addition to HRSA's Medicaid Exclusion File, these tools include claim-line indicators and State-developed lists of covered entities. OIG did not evaluate these tools to determine which is most effective, but does note that any evaluation of these tools should consider, among other things, complications created by contract pharmacy operations, which are highlighted in OIG's 2014 report, *Contract Pharmacy Arrangements in the 340B Program* (OEI-05-13-00431).

   Ongoing OIG work is assessing the tools States use to prevent duplicate discounts for drugs paid through Medicaid MCOs. OIG would be pleased to brief you on the results of that work when it is complete, as well as provide further technical assistance.

4. What is the volume of 340B prescriptions that are going through contract pharmacies?

   OIG is not aware of any available data on the volume of 340B prescriptions going through contract pharmacies. However, OIG's analysis of HRSA's covered entity database shows that about 28 percent of covered entities used contract pharmacy arrangements in 2014.

5. The OIG report found that several contract pharmacy programs do not provide discounts on prescription medicines to uninsured individuals, the increased use of contract pharmacies may be resulting in a greater risk of dispensing 340B drugs where 340B drugs aren't permitted, and the sheer growth of the program heightens the concern that self-policing may be insufficient.

   a. Given these facts, do you think the agency's 2010 contract pharmacy sub-regulatory guidance should be reassessed or reevaluated to determine its appropriateness? What, if any, suggested changes do you have regarding the contract pharmacy program?

      Yes, we think that program rules on contract pharmacies should be updated to address the evolution of the program. OIG suggests that any effort to update program rules governing contract pharmacies should address the following three

topics highlighted in OIG's 2014 report, *Contract Pharmacy Arrangements in the 340B Program* (OEI-05-13-00431).

First, OIG found a lack of clarity in HRSA's patient definition which can make it difficult to determine diversion in certain contract pharmacy scenarios. Updated contract pharmacy guidance should clarify how entities and their contract pharmacies should apply the patient definition in their contract pharmacy arrangements and also take into account the unique situations that contract pharmacies pose in determining eligibility so as to better prevent diversion.

Second, OIG highlighted a lack of clarity about whether covered entities need to extend the discounted 340B price to uninsured patients through their contract pharmacies. Guidance on how the program should apply to uninsured patients in these scenarios should be clarified to ensure that patients are treated consistently across 340B providers and that operations align with the program's intent.

Third, OIG found that entities were not exercising full oversight of their contract pharmacy arrangements. HRSA's 2010 guidance defined suggested practices for covered entity oversight of contract pharmacies but OIG work found that many covered entities did not conduct all of the oversight suggested in the guidance. Updated contract pharmacy guidance could reiterate or strengthen covered entity oversight requirements.

6. In 2010, HRSA issued guidance allowing entities to have an unlimited number of contract pharmacies. Even though the 340B statute does not mention the use of contract pharmacies, it has now become one of the biggest drivers for program growth, and as OIG's 2014 report noted, the use of contract pharmacies creates complications in preventing drug diversion and duplicate discounts. I wondered if the OIG has seen a correlation with increased incidence of duplicate discounts or diversion in contract pharmacies? If so, should certain parameters be in place (e.g., limits on the size or geographic reach of contract pharmacy networks) for contract pharmacies under the 340B programs to ensure program integrity?

   OIG work has identified vulnerabilities related to contract pharmacies but we do not have information about increased incidence of duplicate discounts or diversion in contract pharmacy arrangements. Although OIG work has not evaluated this point or other parameters for contract pharmacies, including geographic reach, OIG's 2014 report, *Contract Pharmacy Arrangements in the 340B Program* (OEI-05-13-00431), found that few covered entities conducted all of the oversight recommended by HRSA in its 2010 contract pharmacy guidance. Greater covered entity oversight of contract pharmacy arrangements would help strengthen program integrity.

7. Do you believe that, with limited dollars and time, scarce resources for oversight should be targeted to the greatest vulnerabilities? If so, what covered entities provide the greatest risk to the integrity and accountability of the program? (Note: while I realize the contract pharmacy vulnerabilities, I'm specifically interested in the type of covered

entity.)

Yes, OIG agrees risk assessments and targeting limited resources for oversight are important. OIG work has not assessed which covered entity types pose the greatest risk to the 340B Program. Regarding vulnerabilities related to contract pharmacies, OIG's 2014 report assessed covered entities' oversight of contract pharmacies and identified general vulnerabilities in contract pharmacy arrangements, but did not to assess which types of covered entities had contract pharmacy arrangements that posed the greatest risk to the program. However, it is true that three types of providers – critical access hospitals, disproportionate share hospitals, and community health centers – most frequently use contract pharmacies.

8. Given HHS OIG's ongoing work, I wondered if the OIG has reviewed whether the growth in the 340B program has shifted the cost to other parts of the health care system. Has the OIG reviewed whether the 340B program has motivated hospitals to acquire practices and the impact of that behavior on the Medicare program because of the reimbursement differences between clinics and hospitals? Has the OIG considered whether the 340B program discourages use of cheaper generic drugs?

   OIG work has focused primarily on program integrity issues and has not reviewed cost shifting, impacts on generic dispensing, or incentives for practice acquisition related to the 340B Program. The OIG work plan is flexible and evolving so we can consider these topics for potential future work. Ongoing OIG work is assessing the prevention of duplicate discounts for drugs paid through Medicaid MCOs. Additional OIG work underway is examining the intersection of the 340B Program and Medicare Part B. We anticipate final reports on these issues in 2015. OIG would be pleased to brief you on the results of that work, including any recommendations, when the reports are complete.

9. National trends in health care provider consolidations have raised concerns from health economists about increased costs to Medicare and the entire health care system. I've heard reports that hospitals are buying up community-based cancer clinics which do not at the time of purchase qualify for the 340B program. However, these clinics are later brought under the hospital umbrella. A June 2014 Berkeley Research Group study estimated that these dynamic led to almost $200 million in additional costs over a three-year period to Medicare beneficiaries who faced greater costs being billed by a hospital. What policy remedies do you envision could reduce costs to seniors?

   OIG work has not addressed this topic; as such we do not have any recommendations at this time.

10. MedPAC's recent public meeting raised the possibility of extending the 340B discount to seniors participating in Medicare. The idea is that Medicare's drug reimbursement is ASP+6, while the 340B program yields savings of 20 to 50 percent off of commercial prices. If Congress were to modify the 340B statute, seniors—and the Medicare Trust Fund—could potentially save money. What considerations—cautions or encouragements—would you offer on this policy proposal?

Additional OIG work underway is examining the intersection of the 340B Program and Medicare Part B and will include estimated savings for Medicare under a number of "shared savings" models and related policy considerations. We anticipate a final report on this topic in 2015 and would be pleased to brief you on the results of that work, including any recommendations, when it is complete.